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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,403	12/12/2001	Robert J. Schwartz	108328.00031	3652

7590 02/23/2006

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,403	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10,12,13,76,80-85,87,88 and 137-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10,12,13,76,80-85,87,88 and 137-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Office Action of August 9, 2005, on November 14, 2005. Claims 1, 8, 76, 83 are amended. Claims 2-4,11, 77-79, 86 are cancelled.

Claims 1, 5-10, 12, 13, 76, 80-85, 87-88, 137-139 are under consideration.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on November 14, 2005. The Examiner has considered the references cited in the IDS.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-10, 12, 13, 76, 80-85, 87, 88, 137, 138 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

a method of improving or enhancing growth in an offspring from a female pig or rat comprising

electroporating an effective amount of a vector into muscle cells by direct injection of the female pig or rat prior to or during gestation of the offspring, wherein the vector is comprised of a nucleic acid sequence encoding SEQ ID NO. 1 or SEQ ID NO. 8, wherein the nucleic acid sequence is operably linked to a hGH3' untranslated region and a eukaryotic promoter, wherein said nucleic acid sequence is expressed in the

female and wherein the expression of said nucleotide sequence results in improved or enhanced growth or rate of growth of the offspring, and wherein the vector is a plasmid,

does not reasonably provide enablement for

a method of improving or enhancing growth in an offspring from any female mammal comprising

electroporating an effective amount of a vector into muscle cells of the female mammal prior to or during gestation of the offspring, wherein the vector is capable of expressing any growth hormone releasing hormone or analog thereof in the female mammal during gestation and wherein the vector comprises a promoter, a nucleotide sequence capable of expressing the GHRH or analog thereof and a 3' untranslated region, under the conditions that promote expression of the nucleotide sequence and wherein the introducing and expression of the nucleotide sequence results in improved or enhanced growth in said offspring, and wherein the vector is a plasmid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record February 25, 2005, August 5, 2005, and August 9, 2005.

Applicant's arguments filed November 14, 2005 have been fully considered and they are persuasive in part.

Before the Examiner responds to the Applicant's response of November 14, 2005, it should be pointed out that the scope of enablement has been amended to include that a eukaryotic promoter could be used in the claimed invention. No

enablement rejection has been applied to the scope of "promoter"; "eukaryotic promoter" had been added to clarify the scope of the claimed invention.

Applicant has overcome the Examiner's rejection regarding the scope of route of vector administration (Applicant's response, page 17, point a; pages 27-28). Applicant has amended the claims such that the route of vector delivery is via "electroporation."

Regarding the issue of the claimed invention encompassing any "growth hormone releasing hormone or analog thereof," (Applicant's response, pages 17-23, point b), the Examiner does not find the Applicant's argument persuasive. The Applicant indicates that "growth hormone," "growth hormone releasing hormone," and "growth hormone releasing hormone analog," are common meanings of the terms and that an artisan of ordinary skill in the art would have understood that thee is an abundance of guidance on both synthetic and naturally occurring GHRH and GHRH analogs, as evidenced in paragraph 11 of the specification (Applicant's response, page 18). Applicant indicates that an artisan of ordinary skill would not have isolated paragraph 51 ("The term, 'growth hormone releasing hormone' as used herein is defined as a hormone which facilitates or stimulates release of growth hormone.") and read it in a vacuum without consideration of the immediate previous paragraphs or out of context with the entire rest of the specification (Applicant's response, page 20). The Examiner disagrees with the Applicant's assertion because "growth hormone releasing hormone" has not been defined exclusively as to be a name for one particular protein; rather, the phrase has been written broadly to encompass any hormone which facilitates or stimulates release of growth hormone. In addition to this, the art, e.g. Anderson et

al., 2004, previously provided, supports the specification's definition by indicating that ghrelin stimulates secretion. As such, in light of the fact that the specification, with support from the art, an artisan would have broadly interpreted the claim to encompass ghrelin and ghrelin's analogs.

With regard to the issue of whether an artisan was enabled to practice the claimed invention for gherlin and grehlin's analogs, the Applicant indicates that support was provided for practicing the claimed invention for ghrelin and indicates paragraph 171 of the specification (Applicant's response, page 21). Paragraph 171 teaches that ghrelin is a ligand that works through the growth hormone secretagogue receptor (GHS-R). Paragraph 172 teaches that a GHS-R ligand is given orally (such as by adding to the feed or drinking water) which would amplify the effects of GHRH on causing release of GH from the pituitary gland. In this embodiment, the GHRH nucleic acid delivery of the present invention would get an added enhancement (Applicant's emphasis). In response, the Examiner does not find the argument persuasive because context that "ghrelin" was being used was that in claim 1, it is readable as a member of a "growth hormone releasing hormone" and that it was a growth hormone releasing hormone that could be electroporated into a female rat or pig and be used to improve or enhance growth in offspring. While the specification teaches that ghrelin could be added to drinking water or feed, nothing in the specification indicates that ghrelin can be introduced via a nucleic acid sequence in a plasmid. No guidance was provided whether electroporation of a vector comprising a nucleic acid sequence encoding ghrelin could be administered to a female mammal, wherein the offspring of the female

mammal would exhibit improved or enhanced growth. Further, no guidance was provided as to what comprise analogs of ghrelin, such that an artisan would know that when expressed in a pregnant female mammal, would result in offspring that exhibit improved or enhanced growth. With regards to the GHRH analogs, while the specification provides guidance as to a variety of different kinds of GHRH analogs, nothing in the specification provides guidance as to which analogs or what characteristics of analogs had activity like HV-GHRH, the analog used in the Examples, such that an artisan would predictably obtain piglets similar to the ones described in the Examples. As such, while the specification provides guidance for using SEQ ID NOs 1 and 8, the specification has not provided guidance for the broad scope of analogs of HV-GHRH and for the broad scope of any growth hormone releasing hormone (including ghrelin) and its analogs.

The Applicant provides an argument that the Hammer et al. 1986 citation should not be used to make a comparison with the instant invention because the Applicant is not using transgenic animals (Applicant's response, point c, pages 23-26, 28-29). In response, the Examiner does not find the argument persuasive because the point of the Hammer et al. citation was that an artisan cannot predict that expression of a heterologous protein would necessarily have activity in a host animal. As such, while the specification provides guidance for the effects on offspring in rats and pigs, the art teaches that an artisan cannot predict that the claimed invention is reasonably predictably for the broad scope of claimed mammals. As such, while there is

enablement for rats and pigs, there is no guidance that the claimed invention can be used in other mammals including primates, cows, and giraffes.

For these reasons, the claimed invention is not enabled for its fullest claimed scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 139 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 139 uses the phrase, "introducing into muscle cells and effect amount of vector into muscle cells by intramuscular injection...". This phrase is redundant. In addition to this, the claim appears to be missing a eukaryotic promoter, which is needed to drive transcription of SEQ ID NO. 1 or SEQ ID NO. 8. A suggested amendment to the claim is: A method of improving or enhancing growth in an offspring from a female pig or rat comprising: introducing an effective amount of vector into the muscle cells of a female pig or rat prior to or during gestation of the offspring, wherein the vector is comprised of a nucleic acid sequence encoding SEQ ID NO. 1 or SEQ ID NO. 8, wherein the nucleic acid sequence is operably linked to a eukaryotic promoter and to a hGH3' untranslated region, wherein the nucleotide sequence is expressed in the female pig or rat and wherein the expression of said nucleotide sequence results in improved or enhanced growth or rate of growth of the offspring, and wherein the vector is a plasmid.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER